

Serial No. 09/577,264

Docket No. 0002.12

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This is a full and timely response to the outstanding final Office Action mailed May 24, 2006. Reconsideration of the application and allowance of presently pending claims as amended, are respectfully requested.

**A. Present Status of Patent Application**

Upon entry of the amendments in this response, claims 56-57 and 60-68 remain pending in the present application. By this Amendment, independent claim 56 was directly amended; and claims 57, 60-65 are indirectly amended as they depend from amended independent claim 57. Claim 66 was objected to as depending from an independent claim, which was itself rejected. In response, Applicant has rewritten claim 66 in independent form, incorporating the limitations of the independent claim from which it previously depended.

Applicant notes that Claim 68, added by Amendment filed 21 March 2006, is currently pending and has not been withdrawn. This claim depends from Independent claim 56. The present Official Action identifies this claim as withdrawn.

It is believed that the foregoing amendments and additions add no new matter to the present application and no estoppels are intended thereby, and are made to place the claims in condition for allowance or appeal.

**B. Response To Rejections****1. Response to Election/Restriction**

As noted previously, claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, and 59 have been withdrawn from consideration as being directed to nonelected subject matter.

Further, as noted in the Response to Restriction and Election of Species Requirement of October 4, 2005, Applicant had traversed the Restriction and Election of

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Species Requirement (and herewith maintains the traverse) on the grounds that the Office has not shown that there would be a serious burden to examine all of the pending claims together. Applicant notes that the Office Action did not include a response to Applicant's argument.

## 2. Objection to Claim 66

Claim 66 was objected to as depending from a rejected base claim. As noted above, Applicant has obviated this objection by rewriting claim 66 in independent form, and as such now believes claim 66 is allowable, and respectfully requests such allowance.

## 3. Rejection under 35 U.S.C. §112

Claims 56-57, 60, 63-65 and 67 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Applicant respectfully disagrees with the position that the use of "comprises" in dependent claim 65 is inconsistent with the use of "consisting essentially of" in Independent claim 56. The "consisting essentially of" claim language modifies **only** the materials constituting the claimed pharmaceutical composition. There is nothing in claim 56 that purports to limit to the **form** such materials may take. The dependent claim 65 is thus entirely consistent in that the claimed pharmaceutical composition may be a powder, or may be other than a powder.

Claims 56 and 57 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, in view of the recitation of treatment of a patient showing no signs of osteoporosis. It is to be noted that enablement is found even if a reasonable amount of routine experimentation is required. *Enzo Biochem Inc v Calgene Inc*, 52 USPQ 2d 1129 (Fed Cir 1999.) Moreover, the *In re Wand* factors are not to be construed as an absolute requirement; not all of the factors need be reviewed when determining whether a disclosure is enabling. *Id.*

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While applicant contends that even the un-amended claim is clear and satisfies 35 U.S.C. §112, Applicant has amended the claim to further clarify the method. In this regard, for purposes of §112, the claimed method is "...administering by inhalation through the mouth an aerosolized bolus of a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant." Thus the treatment is properly the administration of the formulation, to any patient in need of such treatment. Such a claim is absolutely definite and certain. The language of claim 56 does not require "manifestations of a successful treatment." Claim 56 is clear.

Moreover, the amendment does not broaden the claim because "treatment" is a well-known term, and is further well described in the specification generally, and in specific passages, for example:

Pulmonary or respiratory administration of PTH fragments according to the present invention will be useful in the **treatment** of osteoporosis, where the PTH fragment will be administered in combination with vitamin D calcitonin, and/or dietary calcium supplements. Such **treatment** methods are well described in U.S. Pat. Nos. 4,698,328 and 4,833,125, the disclosures of which have previously been incorporated herein by reference. Specification at page 11, lines 20-27.

It is to be noted that US 4,698,328, incorporated by reference describes treatment in the context of the physiological effects of increasing bone mass, or preserving existing bone mass. Thus, whether the formulation is administered to remediate an existing osteoporosis condition, or to mitigate, impede or slow the onset, severity, duration or effects of osteoporosis, it is nonetheless a treatment.

In view of the above, Applicant respectfully requests that this ground of rejection be withdrawn, and claims 56-57, and 60-68 allowed.

### **3. Rejection under 35 U.S.C. §103**

The claims have been rejected based on the presumption that it would have been obvious to one skilled in the art to arrive at the claimed method of administration.

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Applicants respectfully ask the Examiner to reconsider this overbroad presumption. The analysis of obviousness was set forth in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In order to establish a *prima facie* case of obviousness, three basic criteria must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to *modify* the reference or to *combine* the teachings of the references. Second, there must be a reasonable *expectation* of success. Finally, the prior art reference or combined references must teach or suggest *all* the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991; emphasis added).

**WANG in view of NEER**

Claims 56, 57 60, 63, 64, 65 and 67 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,011,678 to WANG et al. in view of U.S. Patent No. 4,698,328 to NEER et al. The Office contends that Applicant's consisting essentially of claim language does not distinguish, as Wang allegedly does not require additional components not claimed by Applicant, *to wit* a steroid. Yet Wang is devoid of any teaching showing a useful formulation in the absence of the steroid. At column 4, lines 42-44, WANG states:

As previously indicated, the composition of the invention for administering a pharmaceutically active substance **contains** a biocompatible, amphiphilic steroid.

The language is unequivocal in the use of the term "contains", which requires the presence of named component. Moreover, at Column 8, lines 6-12, WANG teaches **only** preparations comprising sodium tauro-24, 25 dihydrofusidate (STDHF). Every example (I through V) uses STDHF. In particular, Example V – a preparation for human parathyroid hormone, requires STDHF. Applicant's "consisting essentially of" claim

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form thus patentably distinguishes. NEER fails to cure the deficiencies of WANG. In this regard, NEER suggests **neither** administering by inhalation **nor** a pharmaceutical composition including an aerosol propellant. Further, NEER **teaches away** from the recited pharmaceutical composition. Specifically, NEER discloses a composition comprising a parathyroid hormone or physiologically active fragment thereof, or equivalents thereof, **in combination with** (a) a hydroxylated Vitamin D compound, or a structural or functional analogue thereof, or (b) a dietary calcium supplement. NEER at abstract. These components are described as being **necessary**. *Id.* Accordingly, the envisioned combination fails to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

In view of the above, Applicant respectfully requests that this ground of rejection be withdrawn.

***WANG in view of MORITA***

Claims 56-57, 60, 63-65 and 67 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WANG in view of U.S. Patent No. 4,656,250 to MORITA et al. The Office asserts that MORITA discloses that "the peptide [Nle<sup>8</sup>, Nle<sup>18</sup>, Tyr<sup>34</sup>] PTH(1-34) has advantages over PTH(1-34)." Office Action at 3. The Office then argues that it would have been obvious to "treat osteoporosis by inhaling the PTH(1-34) analog that is disclosed in Morita." *Id.* at 4.

In response, the same arguments made above in regard to WANG are similarly applicable here, i.e. Applicants amended claims fully distinguish over WANG, and MORITA fails to cure the above-noted deficiencies of WANG. Specifically, MORITA suggests neither administering by inhalation nor a pharmaceutical composition including an aerosol propellant. Further, MORITA fails to disclose details about pharmaceutical compositions. Accordingly, the envisioned combination fails to disclose or suggest a pharmaceutical composition consisting essentially of a therapeutically effective amount

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of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

In view of the above, Applicants respectfully request that this ground of rejection be withdrawn.

### Conclusion

In view of the foregoing, Applicants submit that pending claims 56-57, and 60-68 satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

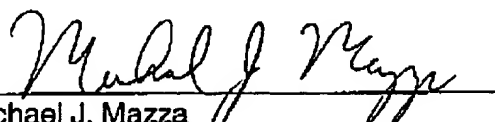
Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 500 348.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 631-3271.

Respectfully submitted,  
Nektar Therapeutics

Date: 1 August 2006

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